REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments as well as the following remarks and that all of the claims remaining be allowed.

Claims Amendments:

Claims 51 and 55 have been amended to recite "exhibits less than 10% crossreactivity", for which support can be found, for example, at page 16, lines 15-23.

Claims 52 and 56 have been amended to recite "a humanized antibody", for which support can be found, for example, at page 23, lines 13-14.

Claims 53 and 57 have been amended to recite "is a neutralizing antibody", for which support can be found, for example, at page 22, line 15.

Claims 54 and 58 have been amended as suggested by the Examiner to clarify the claimed subject matter.

No new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants wish to point out that the amendments presented herein are made merely to clarify the scope of the claimed invention and not to distinguish over any prior art. Thus, Applicants submit that none of the claims now presented or previously presented are obvious over the prior art.

Rejection Under 35 U.S.C. §112, First Paragraph:

(A) The rejection of claims 51-58 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such as way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention, is respectfully traversed for the reasons set forth below.

Pursuant to the *Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, First Paragraph, "Written Description" Requirement* (Federal Register 66 (4): 1099-1111; the "Guidelines")[1], possession may be shown in a variety of ways, such as description of an actual reduction to practice or description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. Federal Register 66 (4), at 1104.

As elaborated below, the written description requirement is satisfied in the instant case under the Guidelines by description of distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

The claimed invention relates to a binding compound comprising an antigen binding site from an antibody, which specifically binds to a mammalian IL-B30/p40 complex or fusion protein, said complex or fusion protein comprising an IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of human or murine origin, wherein said antibody binds an epitope presented by the IL-B30/p40 complex or fusion protein, but exhibits less than 10% crossreactivity with any epitope presented by either IL-B30 alone or p40 alone.

---

[1]The Guidelines, published on January 5, 2001, supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 'Written Description' Requirement" that were published in the Federal Register at 64 FR 71427, Dec. 21, 1999.

The IL-B30 subunit is fully described by virtue of its sequence (SEQ ID NO:2 or 4), and the sequence of the p40 subunit of human or murine origin is known in the art (for example, see page 8, lines 42-47 of the specification). Since the IL-B30/p40 complex consists of only IL-B30 and p40, the amino acid sequences of the complex are adequately disclosed as well. Fusion proteins are also adequately described in the specification, for example, at page 43, first paragraph. It is within the skill in the art to prepare antibodies against the complex or fusion protein, as well as identifying those antibodies that exhibit less than 10% crossreactivity with either IL-B30 alone or p40 alone (see, for example, page 16, lines 15-23). Therefore, the present application provides sufficient distinguishing identifying characteristics, and a skilled artisan would have been able to recognize that Applicants had possession of the claimed invention at the time this application was filed.

The Office Action states that "the specification does not describe a single exemplification of an antibody" as claimed (page 3, last paragraph of the Office Action). However, it is clear that working examples are not required under the written description requirement. The Guidelines explicitly provide that "possession may be shown in a variety of ways", and "description of an actual reduction to practice" is only one of the many ways to satisfy the written description requirement.

The Office Action further states at page 3, last paragraph to page 4, first paragraph that "the specification does not describe a single epitope of an IL-B30/p40 complex or fusion protein that is not shared with either IL-B30 alone or p40 alone", and "Thus the specification does not provide an adequate written description of the invention claimed herein" under *The Regents of the University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). Applicants disagree as the applicable law does not require description of an epitope in the manner prescribed in the Office Action.

In *UC v. Eli Lilly*, the Federal Circuit held that a DNA molecule is not adequately described by the function of the protein it encodes. While the Office Action correctly states

that the principle of *UC v. Eli Lilly* (namely a molecule can not be described by its biological activity only) applies to protein molecules as well as DNA molecules, the required description varies with the nature of the molecule. The Guidelines, which are heavily based on *UC v. Eli Lilly*, state in footnote 42:

> For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes... a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. (emphases added) Federal Register 66(4): 1099, 1110.

The present specification provides sufficient identifying characteristics such as structural formulas, binding specificity and antibody cross-reactivity. Thus, sequences of IL-B30, p40, as well as an exemplary IL-B30/p40 fusion protein are disclosed. The specification also discloses that either IL-B30 alone or p40 alone can not be secreted from cells, while the complex or fusion protein is secreted (page 41, last paragraph to page 42, first paragraph, and page 43, first paragraph). The complex or fusion protein also displays biological activities not possessed by either IL-B30 or p40 alone (pages 43-44). In view of all these differences, a skilled artisan would have been able to conclude that the complex or fusion protein must have a structure different from that of IL-B30 or p40. Indeed, Oppmann et al. (*Immunity* **13**:715-725, 2000, published by the inventors and cited in the Office Action) confirmed that the complex is a disulfide-linked heterodimer between IL-B30 and p40 (page 717, left column, first paragraph). In addition, the specification discloses that "binding composition" refers to molecules that bind with specificity to the IL-B30/p40 complex or fusion protein but not the individual component alone (*e.g.*, page 14, lines 12-14). The specification further discloses how antibodies with less than 10% crossreactivity can be identified (page 16, lines 15-23). Therefore, the present disclosure sufficiently describes the specificity of the claimed antibody as well as the

sequence/structure of the corresponding antigen, which reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention.

Accordingly, the requirement for written description is satisfied, and Applicants respectfully request withdrawal of this rejection.

(B) The Office Action states that claims 53 and 57 allegedly contains new matter because these claims recite "wherein said binding compound neutralizes at least 90% of the bioactivity" of the complex or fusion protein between IL-B30 and p40. As amended, claims 53 and 57 now recite "wherein said binding compound is a neutralizing antibody" instead of the recitation at issue. Therefore, this rejection is now moot and its withdrawal is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph:

The rejection of claims 51-58 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite has been obviated as set forth below.

(A) The Office Action states that the phrase "is not substantially immunologically reactive" in claims 51 and 55 is allegedly indefinite. Since claims 51 and 55 have been amended to recite "exhibits less than 10% crossreactivity" instead of "is not substantially immunologically reactive", this part of the rejection is now moot.

(B) Claims 54 and 58 were deemed indefinite for reading on compositions that depend from compound claims 51 and 55, respectively. As amended, claims 54 and 58 are now directed to compositions comprising the compounds of claims 51 and 55, respectively. Therefore, this part of the rejection is moot.

(C) Claims 52 and 56 were deemed indefinite for reciting "wherein said binding compound is humanized". As suggested in the Office Action, claims 52 and 56 have been

amended to recite "wherein the binding compound is a humanized antibody". Therefore, this part of the rejection is also moot.

Accordingly, withdrawal of the rejection is respectfully requested.

Conclusions:

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's rejections are hereby requested. Allowance of the claims of this application at an early date is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is invited to call the undersigned at (650) 622-2340.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: _____
Ping F. Hwung
Registration No. 44,164

P.O. Box 1404
Alexandria, Virginia 22313-1404
(650) 622-2300

Date: February 27, 2003

Attachment to Amendment and Reply to Office Action mailed February 27, 2003

Marked-up Copy

51. (Amended) A binding compound comprising an antigen binding site from an antibody, which specifically binds to a mammalian IL-B30/p40 complex, said complex comprising an IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of human or murine origin, wherein said antibody [immunologically reacts with] binds an epitope presented by the IL-B30/p40 complex, but [is not substantially immunologically reactive] exhibits less than 10% crossreactivity with any epitope presented by either IL-B30 alone or p40 alone.

52. (Amended) The binding compound of claim 51, wherein said binding compound is a humanized antibody, [a] monoclonal antibody, single chain antibody, Fv fragment, Fab fragment, Fab' fragment, or $F(ab')_2$ fragment.

53. (Amended) The binding compound of claim 51, wherein said binding compound [neutralizes at least about 90% of the bioactivity of human IL-B30/p40 complex] is a neutralizing antibody.

54. (Amended) A composition comprising the [The] binding compound of claim 51 [further comprising] and a pharmaceutically acceptable carrier or diluent.

55. (Amended) A binding compound comprising an antigen binding site from an antibody, which specifically binds to a fusion protein comprising an IL-B30 subunit (SEQ ID NO:2 or 4) and a p40 subunit of human or murine origin, wherein said [binding compound immunologically reacts with] antibody binds an epitope presented by said fusion protein, but [is not substantially immunologically reactive] exhibits less than 10% crossreactivity with any epitope presented solely by either IL-B30 alone or p40 alone.

56. (Amended) The binding compound of claim 55, wherein said binding compound is a humanized antibody, [a] monoclonal antibody, single chain antibody, Fv fragment, Fab fragment, Fab' fragment, or $F(ab')_2$ fragment.

57. (Amended) The binding compound of claim 55, wherein said binding compound is a neutralizing antibody [neutralizes at least about 90% of the bioactivity of said fusion protein].

58. (Amended) A composition comprising the [The] binding compound of claim 55 [further comprising] and a pharmaceutically acceptable carrier or diluent.